The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte
ELISABETH STOCKERT, ELKE JAGER, YAO-TSENG CHEN, MATTHEW SCANLAN, ALEXANDER KNUTH, and LLOYD J. OLD

Appeal 2007-0543
Application 10/023,182
Technology Center 1600

Decided: March 23, 2007

Before TONI R. SCHEINER, LORA M. GREEN, and NANCY J. LINCK, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims directed to a genus of isolated proteins consisting of immunoreactive portions of NY-ESO-1, a protein identified as a tumor rejection antigen precursor. The examiner has rejected the claims under 35 U.S.C. § 112, first paragraph, as lacking adequate written descriptive support. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

BACKGROUND

Major Histocompatibility Complex (MHC) molecules are cellular proteins that form complexes with proteolytic fragments of antigens, and transport those antigen fragments to the cell surface to present them to the body's T cells in order to provoke a specific immune response. A given MHC molecule characteristically recognizes and binds peptides that are similar in size and sequence. Methods of predicting which portions of a given protein are likely to bind a given MHC molecule were known in the art at the time of the invention, as were cytotoxicity assays designed to determine whether a given MHC-bound peptide is capable of provoking a T cell response. Specification 24: 4 to 25: 18.

DISCUSSION

Claims 32, 34-37, and 40, are the subject of this appeal, and are directed to a genus of proteins consisting of immunoreactive portions of NY-ESO-1, a purported tumor rejection antigen precursor encoded by SEQ ID NO: 1. Specifically, the claims are directed to portions of NY-ESO-1 that can be processed by a cell to generate peptides capable of provoking a T cell response after complexing with MHC molecules. Claim 41, also pending, is directed to three specific portions of NY-ESO-1, and has been indicated allowable.

Claim 32 is representative of the subject matter on appeal, and reads as follows:

> 32. An isolated protein consisting of an immunoreactive portion of a protein encoded by an isolated nucleic acid molecule, consisting of the nucleotide sequence of SEQ ID NO: 1, wherein said immunoreactive portion of a protein is processed by a cell to form a peptide which complexes to an MHC molecule and provides a T cell response.

According to Appellants, the cDNA encoding NY-ESO-1 was originally isolated from a library prepared from a specimen of squamous cell cancer of the esophagus (Specification 6: 4-8), and the corresponding mRNA was subsequently detected in other esophageal tumors, as well as tumors of unrelated lineage, including melanoma, and breast (*id.* at 10: 24-26). NY-ESO-1's overall "pattern of expression is consistent with other tumor rejection antigen precursors" (*id.* at 10: 13-14). Moreover, NY-ESO-1 was "found to be reactive with antibodies in the serum of cancer patients" (*id.* at 5: 12-13, 16-17).

In order to evaluate T cell response to NY-ESO-1, the amino acid sequence of the protein encoded by SEQ ID NO: 1 was analyzed, and peptides satisfying the binding motif for the MHC molecule HLA-A2 were tested in cytotoxicity assays (*id.* at 17: 9-11 and 24: 4-11). Of these peptides, three corresponding to SEQ ID NOS: 4, 5, and 6, with the common amino acid sequence SLLMWIT, "were the three best stimulators of CTLs" (*id.* at 25: 1-4). In addition, the deduced protein was analyzed for peptides satisfying other MHC binding motifs (i.e., various HLA-A and HLA-B molecules). Of the thirty-eight such peptides listed in the specification, only a few have sequences overlapping SEQ ID NOS: 3, 4, and 5 (*id.* at 25: 9 to 26: 40). According to Appellants, complexes between these additional peptides and their corresponding MHC molecules "should provoke a cytolytic T cell response" (*id.* at 25: 12-15), which "could be determined by one skilled in the art following [conventional] methods" (*id.* at 25: 16-17).

According to the Examiner, however, "[t]he specification does not provide an adequate written description of the claimed genus" (Answer 10), because the peptides corresponding to SEQ ID NOS: 3, 4, and 5 are not representative of a genus that encompasses "peptides [which] do not have to share the same common structure SLLMWIT of . . . SEQ ID NO[S]: 4, 5 and 6" (Answer 5). As far as the

other thirty-eight peptides listed in the specification are concerned, the Examiner acknowledges that they "have HLA binding motifs, and are expected to bind to HLA molecule[s]" (*id.*), but argues that they are not "adequate examples of the claimed T cell epitopes" (*id.* at 6), because "one cannot predict that these peptides also elicit sufficient T cell response" (*id.* at 5). The Examiner finds that "one of skill in the art would reasonably conclude that Appellant[s] did not have possession of the claimed genus . . . at the time the invention was made" (*id.* at 10).

We disagree with the Examiner's rationale and conclusion. "The 'written description' requirement serves a teaching function, . . . in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 922, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004) (citation omitted). Another "purpose of the 'written description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date [ ], [the applicant] was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). *See also Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1329, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). The requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." *University of Rochester*, 358 F.3d at 928, 69 USPQ2d at 1896. Whether or not a specification satisfies the requirement is a question of fact, which must be resolved on a case-by-case basis (*Vas-Cath*, 935 F.2d at 1562-63, 19 USPQ2d at 1116).

"[A]pplicants have some flexibility in the 'mode selected for compliance' with the written description requirement" (*University of Rochester*, 358 F.3d at 928, 69 USPQ2d at 1896), and it is well settled that actual reduction to practice is

not necessary to satisfy the requirement (*id.* at 926, 69 USPQ2d at 1894). In *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), the court explained that "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus" (*id.* at 1569, 43 USPQ2d at 1406). In addition, the court subsequently clarified that "the written description requirement would be met for [a claim] . . . if [a] functional characteristic . . . were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." *Enzo Biochem*, 296 F.3d at 1324-25, 63 USPQ2d at 1613.

Finally, the court has made it clear that other factors, including the level of knowledge and skill in the art, are relevant to whether a description satisfies § 112. *See Capon v. Eshhar*, 418 F.3d 1349, 1359, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) ("[T]he determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.").

Here the specification discloses more than forty representative peptides. Each of the peptides is structurally identical to a portion of NY-ESO-1, the protein encoded by SEQ ID NO: 1, and each of the peptides was identified on the basis of what was known about MHC binding motifs at the time of the invention. Moreover, at least three of the peptides were shown to meet the functional limitations of the claims using a conventional cytotoxicity assay. We conclude that

the structural constraints placed on the members of the claimed genus, together with what was known in the art at the time of the invention about MHC binding motifs, and about detecting T cell response, provides more than enough detail to allow a person skilled in the art to understand and recognize what is claimed, and conveys with reasonable clarity to one of skill in the art that Appellants were in possession of the claimed genus at the time of the invention.

SUMMARY

The rejection of claims 32, 34-37, and 40 under 35 U.S.C. § 112, first paragraph, for lack of adequate written descriptive support is reversed.

REVERSED

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